

Variances and Exceptions to Laboratory Operations Requirements

Los Alamos National Laboratory
Laboratory Implementation Requirements LIR 301-00-02.3
Original Issue Date: February 27, 1997 (Revised: 04/27/00)

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Introduction

Lessons Learned

Note: [Click here](#) for Lessons Learned *that may apply* to the requirements contained in this LIR.

1.1 Overview

This LIR establishes the requirements that must be followed when requesting a variance or an exception, in total or in part, to the requirements contained in an LPR (Laboratory performance requirements) or LIR document.

The requirements in this LIR shall be effective upon the revision date.

This LIR complements the expectations contained in LPR 300-00-00.

See Attachment 3, “Recommended Major Implementation Criteria for Self-Assessment.”

1.2 In this Document

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2.0 Applicability

The requirements stated in this LIR shall apply to any request for a variance to the requirements contained in an LPR or LIR or an exception to the requirements contained in an LIR.

3.0 Definitions

action DD/PD/OD (action director)—the division director, program director, or office director with ultimate responsibility for the content of operations requirements and guidance.

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applicable—for the purpose of this LIR, applicable means that the requirements contained in a document have relevance or a valid connection to the work and hazards associated with an organization's operations.

DLD-OPS—Deputy Laboratory Director for Operations

exception—for the purpose of this LIR, an exception is full relief from specific implementation of all or a part of the requirements contained in an LIR that is applicable to an organization.

LIR—Laboratory implementation requirements

LPR—Laboratory performance requirements

LSRP/ESH-OIO—Laboratory Standards Requirements Project

not applicable—for the purpose of this LIR, not applicable means that the requirements contained in a document have no relevance or valid connection to the work and hazards associated with an organization's operations.

OIC—office of institutional coordination

POC—point of contact

variance—a deviation from the explicit requirements contained in an LPR or LIR.

4.0 Precautions and Limitations

The Laboratory shall not approve a request for a variance or exception if its implementation would violate Federal or State law or requirements included in the UC/DOE contract.

5.0 Implementation Requirements

5.1

Criteria

Variance.

Guidance Note: Variances may be requested and approved for both LPRs and LIRs.

Requests for a variance must contain the following criteria:

- (1) a detailed justification for the request, including the circumstances that dictate implementation actions differing from the specific implementation requirements contained in an LPR or LIR to which the variance is being requested;

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5.1

Criteria (cont)

- (2) a description of the compensatory measures that ensure protection will meet or exceed that provided by the requirements contained in the LPR or LIR to which the variance is being requested; and
- (3) a specified duration of the variance not to exceed 3 years from the date of approval.

Form 1661a, "Laboratory Operations Requirements Variance Form," (see Attachment 1) must be completed and the process required by the form must be followed when requesting and approving a variance to an LPR or LIR.

Any changes to the originally requested variance or its duration shall be agreed upon between the requesting and action Division Director/Program Director/Office Director (DD/PD/OD) and shall be documented on Form 1661a (see Sec. 9 of the form).

Exception. The following criteria shall apply to requests for exceptions:

- Exceptions can be approved *only* for LIRs; exceptions for LPRs shall not be granted.
- Exceptions shall be limited to an activity *not* satisfied by a variance.
- The DLD-OPS must approve exceptions to LIRs and that approval indicates acceptance of the risk incurred by the exception.

Requests for exceptions to LIRs must contain the following:

- (1) a detailed justification, including an assessment of the risk if the exception is approved.

The rigor of this assessment shall be sufficient to satisfy the action director and DLD-OPS. The level of rigor shall be graded based on the risk.

Guidance note: The requesting director or designee should contact the OIC to clarify the expected level of rigor.

- (2) a specified duration not to exceed 3 years from the date of approval.

Form 1661b, "Laboratory Operations Requirements Exception Form," (see Attachment 2) must be completed and the process required by the form must be followed when requesting and approving an exception to an LIR.

Any changes to the originally requested exception or its duration shall be agreed upon by the requesting and action Division Director/Program Director/Office Director (DD/PD/OD) and shall be documented on Form 1661b (see Sec. 9 of the form).

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5.2

Requesting DD, PD, or OD (or designee)

The DD/PD/OD (or designee) requesting a variance to an LPR or LIR or an exception to an LIR must ensure that

- a detailed justification for the request, proposed compensatory measures, and duration of the variation are stated in or attached to Form 1661a or Form 1661b.
 - the process in Form 1661a or Form 1661b is followed, and that the form is completed and signed.
 - an assessment of the risk for an LIR *exception* is included on Form 1661b.
 - agreement is reached with the action director if the proposed content or duration of the requested variance or exception is changed from the initial request.
 - concerns that arise are resolved at the POC/OIC level, or if required, at the DD/PD/OD level. If agreement cannot be achieved at either of these levels, the request and its supporting concerns and justification must be presented through the ISM Program Manager to the Deputy Laboratory Director for Operations (DLD-OPS) for resolution.
 - the action DD/PD/OD is notified and the process in Form 1661a or Form 1661b, is followed whenever a renewal or extension of or modification to an approved variance or exception is required.
 - the variance or exception is implemented as approved.
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5.3

Action DD/PD/OD (or designee)

Variance and Exception. The action director (or designee) responsible for the LPR or LIR to which a variance or exception request is being made must

- ensure that prior to the expiration date for which a variance or exception has been approved, the requesting director is notified that the variance or exception will become invalid. The action director must consult the requesting director to determine if a variance or exception renewal/extension is required, depending upon whether or not the LIR remains unchanged or is revised.
- ensure during any review or revision of an LIR or LPR that the existence, content, and experience with associated variances and exceptions are considered with the purpose of improving the LIR/LPR thereby eliminating the need for the variances/exceptions.
- ensure that within 15 working days
 - (1) the request (i.e., for the proposed, modified, or extended variance or exception) is approved, denied, or other instructions are provided to the requesting DD/PD/OD (director);

5.3

- (2) a copy of the signed original form is forwarded to the requesting director
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Action
DD/PD/ OD
(or designee)

(or POC); and

(3) a copy of the request is sent to LSRP/ESH-OIO.

- notify the requesting director if any change to a proposed variance or exception, including the duration, is to be made and receive concurrence from the requesting director. The concurrence shall be documented by both the requesting director and the action director by signing Sec. 9 of Form 1661a or Form 1661b.
- accompany the requesting director to the DLD-OPS if the request or its duration cannot be resolved at the DD/PD/OD management level.

Variance. The action director (or designee) responsible for the LPR or LIR to which a variance request is being made must

- ensure that the process in Form 1661a is followed and the form is completed and signed.
- ensure that the proposed compensatory measures provide protection that meet or exceed those provided by the requirements contained in the LPR or LIR to which the variance is being requested.
- ensure that the period for which the variance is approved does not exceed the required 3-year review date for the LIR to which the variance is requested.
- ensure that each time an LIR is reviewed or revised, any approved variances to that LIR are reviewed for extension, modification, or deletion. Ensure that the requesting director is notified of the results of that review, including any actions that should be taken. If there have been no revisions to the LIR before the required 3-year LIR review date, any variances to the LIR must be reviewed at that time for extension, modification, or deletion.

Exception. The action director (or designee) responsible for the LIR to which an exception request is being made must

- ensure that the process in Form 1661b is followed and the form is completed and signed.
- ensure that a risk assessment is included in the request for an exception.
- evaluate the risk assessment to determine if it is valid and accurate.
- ensure that the period for which the exception is approved does not exceed the required 3-year review date for the LIR to which the exception is requested.
- ensure that each time an LIR is reviewed or revised, any approved exceptions to that LIR are reviewed for extension, modification, or deletion. Ensure that the requesting director is notified of the results of that review, including any actions that should be taken. If there have been no revisions to the LIR before the required 3-year LIR review date, any exceptions to the LIR must be

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reviewed at that time for extension, modification, or deletion.

5.4 Requesting Directorate Point of Contact

The requesting director's POC, when acting on behalf of their director's organization, (1) must complete sections 1-6 (and if required, Sec. 9) of the forms, and (2) must ensure that a copy of Form 1661a or Form 1661b following the approval or disapproval by the action DD (with *all* sections completed and signed) is maintained by the requesting organization for the duration of the variance/exception or for 3 years, whichever is longer.

5.5 Action DD/PD/OD's Offices of Institutional Coordination

The offices of institutional coordination (OICs), being responsible for the requirements contained in their LPRs or LIRs, must

- provide to the requesting DD/PD/OD (or designee), or their POC, any assistance required to ensure a comprehensive recommendation is provided to the action director or designee for approval or denial of the request;
 - ensure that required quality criteria are considered when granting the variance or exception;
 - respond in writing through the action director to the requesting director (or designee) with approval/denial or other instruction to the variance or exception request within 15 working days;
 - assist the action DD in completing sections 7 and 8 in Forms 1661a and 1661b; and
 - review each variance and exception (1) every time the LPR (for variances only) or LIR is revised, or (2) at the required 3-year review of the LIR if the LIR has not been reviewed previously and notify the requesting DD/PD/OD of the results of the review.
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5.6 DLD-OPS

Variance. The DLD-OPS must provide resolution to a requested variance when agreement on compensatory measures or duration cannot be reached at the DD/PD/OD management level and complete sections 9 and 10 in Form 1661a.

Exception. The DLD-OPS must approve or deny all exception requests and complete sections 9 and 10 in Form 1661b.

5.7 LSRP/ESH- OIO

The LSRP/ESH-OIO must maintain

- the Web site listing of variances and exceptions; and
 - the record copy of the completed and signed Forms 1661a and 1661b.
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6.0 References

The OIC for this document shall be the LSRP/ESH-OIO, 665-4965
(policy@lanl.gov).

7.0 Attachments

Attachment 1. Laboratory Operations Requirements Variance Form (Form 1661a)
Attachment 2. Laboratory Operations Requirements Exception Form (Form 1661b)
Attachment 3. Recommended Major Implementation Criteria for Self-Assessment.

Laboratory Operations Requirements Variance Form

The requesting DD/PD/OD (or POC) shall complete items 1-6.

1. Variance to LPR(s) or LIR(s) document number:

Title	Section/Page
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2. Variance (Use continuation sheet if necessary.)

3. Justification (Use continuation sheet if necessary.)

4. Applicable compensating measures (Use continuation sheet if necessary.)

5. Variance being requested for (specify dates or duration):

6. Requesting DD/PD/OD (or designee) must sign this section of the variance request.

Requesting DD/PD/OD (Print)	Title	Signature	Date
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The requesting DD/PD/OD (or POC) shall forward a copy of the request form to the Action DD/PD/OD (or POC) and a copy to the LSRP/ESH-OIO, MS C303.

The action DD/PD/OD (or designee) shall complete items 7-8 within 15 working days.

7. Variance: ☐ Approved for a duration of: _____ ☐ Denied ☐ Other (Use continuation sheet if necessary.)

8. Action DD/PD/OD (Print)	Title	Signature	Date
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The action DD/PD/OD (or POC) shall send a copy of the original form indicating approval/denial to the requesting DD/PD/OD (or POC) and shall send a copy of the form to the LSRP/ESH-OIO for record retention.

9. Requesting and Action Directors concur with changes made to this request for variance: Date:

Requesting Director (sign) _____ Action Director (sign) _____

The DLD-OPS shall approve/deny the variance if/when resolution is not reached at the requesting and action DD/PD/OD level.

10. Variance ☐ Approved for a duration of: _____ ☐ Denied ☐ Other (Use continuation sheet if necessary.)

11. DLD-OPS (Print)	Signature	Date
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Laboratory Operations Requirements Exception Form

<i>The requesting DD/PD/OD (or POC) shall complete items 1-6.</i>			
1. Exception to LIR(s) document number:			
Title		Section/Page	
2. Exception (Use continuation sheet if necessary.)			
3. Justification (Use continuation sheet if necessary.)			
4. Risk Assessment (Use continuation sheet if necessary)			
5. Exception being requested for (specify dates or duration):			
6. Requesting DD/PD/OD (or designee) must sign this section of the exception request.			
Requesting DD/PD/OD (Print)	Title	Signature	Date
<i>The requesting DD/PD/OD (or POC) shall forward a copy of the request form to the Action DD/PD/OD (or POC) and a copy to the LSRP/ESH-OIO, MS C303.</i>			

<i>The action DD/PD/OD (or designee) shall complete items 7-8 within 15 working days.</i>			
7. Exception: <input type="checkbox"/> Approved for a duration of: _____ <input type="checkbox"/> Denied <input type="checkbox"/> Other (Use continuation sheet if necessary.)			
8. Action DD/PD/OD (Print)	Title	Signature	Date
<i>The action DD/PD/OD (or POC) shall send a copy of the original form indicating approval/denial to the requesting DD/PD/OD (or POC) and shall send a copy of the form to the LSRP/ESH-OIO for record retention.</i>			
9. Requesting and Action Directors concur with changes made to this request for exception: Date:			
Requesting Director (sign) _____		Action Director (sign) _____	
<i>The DLD-OPS shall approve/deny all exceptions.</i>			
10. Exception <input type="checkbox"/> Approved for a duration of: _____ <input type="checkbox"/> Denied <input type="checkbox"/> Other (Use continuation sheet if necessary.)			
11. DLD-OPS (Print)	Signature		Date

Guidance

Attachment 3

Recommended Major Implementation Criteria for Self-Assessment

(Non-Mandatory)

LIR Title	LIR Number
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The major implementation criteria listed below are provided to assist Laboratory organizations assess their implementation of this LIR. These criteria provide an objective basis for self-assessing implementation of the major requirements contained in the LIR. The LIR also states requirements in other areas, such as, scope, precautions, and responsibilities that, when applied, complement the successful implementation of these major requirements.

- 1. The most important criterion for assessing the implementation status of this LIR should be, if applicable: Have the requirements contained in the LIR been communicated to the individual(s) responsible for performing the work?**
- 2. In addition, the recommended major implementation criteria for self-assessment of this LIR are the following:**

Requesting director:

- For variances, justify fully the requested variance and list prepared compensation measures, if any are envisioned; for exceptions, justify fully the requested variance and provide risk assessment.
- Complete Form 1661a or Form 1661b and follow its process.
- Ensure all deviations from an LIR have an approved variance or exception in effect and all deviations from an LPR have an approved variance in effect.

Action director:

- Follow the process on Form 1661a or Form 1661b.

DLD-OPS:

- Approve any exceptions to LIRs.
- Approve or deny variance requests when resolution is brought to the DLD-OPS level.